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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,535	03/12/2004	Bruce Sullenger	00-888-K	7840

7590 09/27/2005

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,535	SULLENGER ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/04/04* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. Claims 13-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,667,969 in view of Goyette et al (Mol. Cell. Biol. (1992) 12(3):1387-1395).

Claims 1-7 of U.S. Patent No. 5,667,969 teach a method for splicing a non-viral target nucleic acid molecule within a cell in culture with a separate nucleic acid molecule, wherein said target molecule is deleterious to the cell in which it is located, and wherein said separate nucleic acid molecule is adapted to form a non-deleterious target molecule when spliced with at least a part of said target nucleic acid molecule, comprising the step of: contacting said target nucleic acid molecule with a catalytic nucleic acid molecule comprising said separate nucleic acid molecule under conditions in which at least a portion of said separate nucleic acid molecule is spliced with at least a portion of said target nucleic acid molecule to form said non-deleterious nucleic acid molecule, and wherein said catalytic nucleic acid molecule is active to cleave said target nucleic acid molecule and to splice said separate nucleic acid molecule with said target nucleic acid molecule, and wherein said catalytic nucleic acid molecule is a group I or group II intron molecule and wherein said contacting is in vitro and wherein said target nucleic acid is an RNA molecule and wherein said separate nucleic acid molecule is an RNA molecule and wherein said contacting comprises providing a vector encoding said catalytic nucleic acid molecule comprising said separate nucleic acid molecule.

Claims 1-7 of U.S. Patent No. 5,667,969 represent a species of the more generic claims currently pending which are not limited to analysis of p53.

Goyette teaches a motivation to perform gene correction on p53 (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize p53 as the target gene for correction in the method of claims 1-7 of U.S. Patent No. 5,667,969 since Goyette teaches that "Mutations of p53 have been observed in a wide variety of human cancers (see page 1388, column 1)." Goyette teaches regarding correction of p53 that "it is clear that the correction of these alterations has differing potencies in affecting the malignant behavior of the cells (see page 1393, column 1)." Goyette notes that the correction "illustrates the potent growth-restricting property of wild-type p53 in colorectal cells that do not express the wild-type form (see page 1393, column 1)." Thus, an ordinary practitioner, intent on verifying and expanding the studies of Goyette on p53, would have been motivated to apply the method of claims 1-7 of U.S. Patent No. 5,667,969 since this would be a more specific gene correction technique than the whole chromosome insertion of chromosome 17 performed by Goyette. The ordinary practitioner would prefer the more targeted approach to gene correction in order to study the effects of tumor suppressor genes since "correction of only a single defect can have significant effects in vivo and/or in vitro" (see abstract of Goyette).

2. Claims 13-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-6 of U.S. Patent No. 5,869,254 in view of Goyette et al (Mol. Cell. Biol. (1992) 12(3):1387-1395).

Claims 1-6 of U.S. Patent No. 5,869,254 teach a method for splicing a non-viral target nucleic acid molecule with a separate nucleic molecule comprising a catalytic nucleic acid molecule, wherein said target nucleic acid molecule includes a nucleic acid sequence deleterious to an organism in which it is located, and wherein said separate nucleic acid molecule is adapted to correct said defect after splicing with said target molecule, comprising the step of: contacting said target nucleic acid molecule in a cell in vitro with said separate nucleic acid molecule comprising a catalytic nucleic acid molecule in the presence of one or more spliceosomes or splicing factors under conditions in which at least a portion of said separate nucleic acid molecule is spliced with at least a portion of said target nucleic acid molecule to form a non-deleterious nucleic acid molecule. Also taught is a method wherein said catalytic nucleic acid molecule is active to cleave said target nucleic acid molecule and to splice said separate nucleic acid molecule with said target nucleic acid molecule and wherein said catalytic nucleic acid molecule is a group I or group II intron molecule. Also taught is wherein said target nucleic acid molecule is an RNA molecule and wherein said contacting comprises providing an expression vector encoding said separate nucleic acid molecule.

Claims 1-6 of U.S. Patent No. 5,869,254 represent a species of the more generic claims currently pending which are not limited to analysis of p53.

Goyette teaches a motivation to perform gene correction on p53 (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize p53 as the target gene for correction in the method of claims 1-6 of U.S. Patent No. 5,869,254 since Goyette teaches that "Mutations of p53 have been observed in a wide variety of human cancers (see page 1388, column 1)." Goyette teaches regarding correction of p53 that "it is clear that the correction of these alterations has differing potencies in affecting the malignant behavior of the cells (see page 1393, column 1)." Goyette notes that the correction "illustrates the potent growth-restricting property of wild-type p53 in colorectal cells that do not express the wild-type form (see page 1393, column 1)." Thus, an ordinary practitioner, intent on verifying and expanding the studies of Goyette on p53, would have been motivated to apply the method of claims 1-6 of U.S. Patent No. 5,869,254 since this would be a more specific gene correction technique than the whole chromosome insertion of chromosome 17 performed by Goyette. The ordinary practitioner would prefer the more targeted approach to gene correction in order to study the effects of tumor suppressor genes since "correction of only a single defect can have significant effects in vivo and/or in vitro" (see abstract of Goyette).

3. Claims 13-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,897,016 in view of Goyette et al (Mol. Cell. Biol. (1992) 12(3):1387-1395).

Claims 1-5 of U.S. Patent No. 6,897,016 teach a Method for splicing a target RNA molecule comprising a mutant beta-globin nucleotide sequence within a cell in

culture with a separate RNA molecule comprising a wild type beta-globin nucleotide sequence, wherein a protein product of the target RNA molecule is deleterious to the cell in which it is located, and wherein the separate RNA molecule is adapted to form a target RNA molecule with the wild type beta-globin nucleotide sequence in place of mutant beta-globin nucleotide sequence when spliced with at least a part of the target RNA molecule, the method comprising: contacting the target RNA molecule with a catalytic RNA molecule comprising the separate RNA molecule, under conditions in which at least a portion of the separate RNA molecule is spliced with at least a portion of the target RNA molecule to form the target RNA molecule with the wild type beta-globin nucleotide sequence in place of mutant beta-globin nucleotide sequence when spliced with at least a part of the target RNA molecule.

Claims 1-5 of U.S. Patent No. 6,897,016 represent a species limited to Beta globin but does not teach p53 analysis.

Goyette teaches a motivation to perform gene correction on p53 (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize p53 as the target gene for correction in the method of claims 1-5 of U.S. Patent No. 6,897,016 since Goyette teaches that "Mutations of p53 have been observed in a wide variety of human cancers (see page 1388, column 1)." Goyette teaches regarding correction of p53 that "it is clear that the correction of these alterations has differing potencies in affecting the malignant behavior of the cells (see page 1393, column 1)." Goyette notes that the correction "illustrates the potent growth-restricting property of wild-type p53 in colorectal cells that do not

express the wild-type form (see page 1393, column 1)." Thus, an ordinary practitioner, intent on verifying and expanding the studies of Goyette on p53, would have been motivated to apply the method of claims 1-5 of U.S. Patent No. 6,897,016 since this would be a more specific gene correction technique than the whole chromosome insertion of chromosome 17 performed by Goyette. The ordinary practitioner would prefer the more targeted approach to gene correction in order to study the effects of tumor suppressor genes since "correction of only a single defect can have significant effects in vivo and/or in vitro" (see abstract of Goyette).

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 102

5. The rejection of claims 1-9, 11 and 12 under 35 U.S.C. 102(b) as being anticipated by Haseloff et al (WO 92/13090) is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 103

6. The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Haseloff as applied to claims 1-9, 11 and 12 and further in view of Weber et al (J. Gen. Virol. (1992) 73:2955-2961) is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

7. The rejection of claims 1-4 and 6-12 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendment.

Response to Arguments

8. Applicant's arguments filed August 22, 2005 have been fully considered but they are not persuasive.

The only remaining rejections are the double patenting rejections. These rejections remain applicable and no terminal disclaimer has yet been filed. While there was a response to the rejection, no specific argument was presented to overcome the rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman

JEFFREY FREDMAN
PRIMARY EXAMINER
9/22/07